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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/528,923	03/23/2005	James P Nakas	Suny-0004US	8887

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EXAMINER

PROUTY, REBECCA E

ART UNIT	PAPER NUMBER
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1652

NOTIFICATION DATE	DELIVERY MODE
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02/08/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

PTOCommunications@hwdpatents.com

Office Action Summary	Application No. 10/528,923	Applicant(s) NAKAS ET AL.	
	Examiner Rebecca E. Prouty	Art Unit 1652	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 21 November 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,3-7 and 9-18 is/are pending in the application.
- 4a) Of the above claim(s) 10-17 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1, 3-7, 9, 18 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

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Claims 2 and 8 have been canceled. Claims 1, 3-7, 9-17 and newly presented claim 18 are still at issue and are present for examination.

Applicants' arguments filed on 11/21/07, have been fully considered and are deemed to be persuasive to overcome some of the rejections previously applied. Rejections and/or objections not reiterated from previous office actions are hereby withdrawn.

Claims 10-17 remain withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected invention, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 6/3/07.

Claim 8 is objected to because of the following informalities: the claim recites that the ratio of xylose to levulinic acid in the medium after the second addition of levulinic acid is from about 0.01 to 1.0. However this should clearly recite the ratio of levulinic acid to xylose as in all instances described in the specification the amount of xylose is greater than the amount of levulinic acid used. Appropriate correction is required.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

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(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1, 3-7, 9 and 18 are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Lee, Ramsay et al., Bertrand et al., Chung et al. and Jang et al. (all cited on the IDS of 9/16/05).

Each of Lee, Ramsay et al. and Bertrand et al. teach the production of the polyhydroxyalkanoate PHB with a microorganism using the sugar xylose as the main carbon source. Each of Ramsay et al. and Bertrand et al. specifically derived the xylose used for the PHB production from a hemicellulose hydrosylate. None of Lee, Ramsay et al. and Bertrand et al. used levulinic acid as a cosubstrate for the production of P(3HB-co-3HV).

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Each of Chung et al. and Jang et al. teach the production of the polyhydroxyalkanoate P(3HB-co-3HV) with a microorganism using glucose as a primary carbon source and levulinic acid as a secondary carbon source. Chung et al. used ratios of levulinic acid/glucose of 0-0.2 while Jang et al. used ratios of 0-0.1. They teach that P(3HB-co-3HV) is a particularly useful PHA having a range of desirable thermomechanical properties of interest and that levulinic acid is cheaper and more effectively utilized as a cosubstrate for production of P(3HB-co-3HV) than other known cosubstrates. Chung et al. also teach addition of additional amounts of levulinic acid to the culture after an period of several hours in order to maintain the level of LA in the culture at a constant amount and Jang et al. and Chung et al. teach that the ratio of HV to HB can be modulated by adjusting the ratio of the primary and secondary carbon sources, i.e., increased amounts of HV in the copolymer are produced by increased amounts of the cosubstrate. Furthermore, Jang et al. teach that low levels of levulinic acid addition (i.e., 0.5 g/L) was very effective for stimulating cell growth as well as for copolymer accumulation (see page 222).

The skilled artisan is well aware that PHA accumulation in most microorganisms does not occur linearly during the growth phase but occurs only after nitrogen depletion of media begins

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(see Figure 2 of Bertrand and Fig 1 of Ramsey et al.) and that cosubstrates used to produce the HV unit of P(3HB-co-3HV) are often growth inhibitory at high concentrations. As such many P(3HB-co-3HV) cultivations are done as two stage cultivations including an initial growth phase on the primary substrate followed by addition of the cosubstrate at the time of nitrogen depletion and PHA accumulation. However, as Jang et al. teach that low levels of levulinic acid are actually growth stimulatory and as Lee, Ramsay et al. and Bertrand et al. all teach that xylose is a much cheaper primary carbon source for PHB production, it would have been obvious to add low amounts of levulinic acid to the cultures of the microorganisms of any of Lee, Ramsay et al. and Bertrand et al. at the beginning of the culture and to add a larger amount of levulinic acid as a cosubstrate at the time of nitrogen depletion (at approximately 16-30 hrs in the cultures of Bertrand et al. and Ramsey et al., see Figure 2 of Bertrand and Fig 1 of Ramsey et al.) in order to produce P(3HB-co-3HV) in these microorganisms from the cheaper primary carbon source xylose.

Applicants argue that neither Chung et al. nor Jang et al. teach or suggest the use of xylose as a primary carbon source. This is noted but applicants are reminded that the rejection was not made over only the Chung et al. and Jang et al. references

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but over the combination of these references with Lee, Ramsay et al. and Bertrand et al. Each of these three references teach the use of xylose as the primary carbon source for PHB production and why (i.e., cheaper cost of xylose) a skilled artisan would select xylose as primary carbon source instead of glucose as used by Chung et al. and Jang et al. As such the combination of reference cited by the examiner does suggest the use of xylose as the primary carbon source.

Applicants further state that the Office concedes that neither Lee, Ramsay et al., nor Bertrand et al. teach the use of levulinic acid as a cosubstrate for the production of the copolymer and thus none of the cited references provides the suggestion or motivation to combine or modify the teachings of any other cited reference and the Office fails to provide any such reason. However this is not persuasive as the references of Chung et al. and Jang et al. clearly provide the motivation to add levulinic acid as a cosubstrate. Both of these references teach that P(3HB-co-3HV) is a particularly useful PHA having a range of desirable thermomechanical properties of interest and that, production of this polymer requires the addition of a cosubstrate which provides for the synthesis of the HV monomer and that levulinic acid is cheaper and more effectively utilized as a cosubstrate for production of P(3HB-

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co-3HV) than other known cosubstrates. As such these references clearly do provide the motivation to use levulinic acid as a cosubstrate in the methods of Chung et al. and Jang et al.

Finally applicants argue that Claim 1 has been amended to include the limitation that a second, larger quantity of levulinic acid is added between about 16 hours and about 24 hours after the addition of a first, smaller quantity of levulinic acid and that none of the cited references teaches or suggests a second, larger addition of levulinic acid. However, this has been addressed above. As discussed in the rejection the disclosure of Jang et al. teaches that low levels of levulinic acid are growth stimulatory while both Jang et al. and Chung et al. teach that high levels of LA increase the mol % of Hv in the copolymer but are growth inhibitory. As such it would be obvious to add a growth stimulatory amount of LA at the beginning of the growth phase of the culture (before PHA production begins) and then to add additional higher levels of LA as necessary for copolymer production at the time of nitrogen depletion in order to provide to for production of the P(3HB-co-3HV). As such the references do not explicitly suggest the added limitation of the amended claims the teaching of the cited references in combination with the knowledge of the skilled artisan would have suggested this method.

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THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Rebecca E. Prouty whose telephone number is 571-272-0937. The examiner can normally be reached on Tuesday-Friday from 8 AM to 5 PM. The examiner can also be reached on alternate Mondays

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (571) 272-0928. The fax phone number for this Group is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system,

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see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

/Rebecca Prouty/
Primary Examiner
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